

entry of the instant amendment, claims 1, 4, 5, 11-13, 36, 37, and 45-51 will be under consideration, claims 2 and 3 having been cancelled herein, and claims 45-51 having been added herein. Claims 45-51 are supported throughout the specification, e.g., at page 2, lines 1-29, page 3, line 31 to page 4, line 8, page 6, lines 1-6, page 11, lines 26-28, page 26, line 16, page 5, lines 7-8, and Examples 3 and 4. No new matter has been added.

The 35 U.S.C. §112, first paragraph, rejections

(a) Claims 1, 11-13, and 36-37 stand rejected on the grounds that the specification is allegedly not enabling for the full scope of the claims.

The Examiner acknowledges that the specification is “enabling for an isolated DNA molecule that comprises a nucleic acid sequence that hybridizes under highly stringent conditions over the full length of the complement of a sequence that encodes a polypeptide with an amino acid sequence of SEQ ID NO:1 or SEQ ID NO:3, wherein the nucleic acid sequence encodes a polypeptide with the ability to co-stimulate a T cell . . .” (Office Action, page 15-20; emphasis added). From the comments on page 2, line 15, to page 6, line 15, of the Office Action, Applicant understands the Examiners position to be that the isolated DNA molecules covered by the above listed claims are not enabled by the specification. While not agreeing with this position, in order to expedite prosecution of the instant application, Applicant has amended claim 1 to specify DNA molecules containing (a) nucleic acid sequences that encode full-length polypeptides with SEQ ID NO:1 or SEQ ID NO: 3 or these polypeptides but with one or more conservative substitutions, or (b) the complements of such nucleic acid sequences. This amendment is supported by the specification, e.g., at page 1, line 1 to page 2, line 16, and page 4, lines 3-8. Applicant respectfully submits that using the teaching and guidance of the specification (e.g., that on page 4, lines 3-8, and Examples 3 and 4), one of skill in the art would by entirely routine experimentation be able to test whether polypeptides (encoded by the nucleic acids of the invention) containing conservative substitutions of interest retained the ability to co-stimulate a T cell.

Claims 2 and 3 are cancelled without prejudice. Claims 4 and 5 are amended for greater clarity.

(b) Claims 1, 11-13, and 36-37 stand rejected as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, has possession of the claimed invention.

From the comments on page 7, line 2, to page 8, line 13, of the Office Action, Applicant understands the Examiner's position to be that the specification does not provide written description of the functional fragments, variants, or homologs of SEQ ID NO:1 and SEQ ID NO:3 encoded for by the claimed DNA molecules or define the degree of complementarity between the nucleic acids sequences disclosed in the specification and those covered by the instant claims. While disagreeing with this position, Applicant submits that it is rendered moot by the above-described amendment to claim 1.

In light of the above considerations, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

The 35 U.S.C. §112, second paragraph, rejection

Claims 1-5, 11-13, and 36-37 stand rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

From the comments on page 9, lines 1-9 of the Office Action, Applicant understands the Examiner's position to be that the term "stringent conditions" in claim 1 renders the listed claims indefinite. While not necessarily agreeing with this position, Applicant submits that it is rendered moot by the above-described amendment to claim 1.

In light of the above consideration, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

The 35 U.S.C. §102(e) rejection

Claims 1, 11-13, and 36-37 stand rejected as allegedly being anticipated by U.S. Patent No. 5,858,776 (the '776 patent).

From the comments on page 9, line 18 to page 10, line 10, of the Office Action, Applicant understands the Examiner's position to be that, in so far the as the instant claims cover DNA molecules that contain nucleic acids that hybridize under "stringent conditions" to the

Applicant : Lieping Chen
Serial No. : 09/451,291
Filed : November 30, 1999
Page : 6

Attorney's Docket No.: 07039-187001

complement of a sequence that encodes a polypeptide with an amino acid with SEQ ID NO:1 or SEQ ID NO:3, the instant claims are anticipated by the disclosure in the '776 patent of amino acid sequences of human and mouse B7.1 and the nucleotide sequences of cDNA encoding them. While disagreeing with this position, Applicant submits that it is rendered moot by the above-described amendment to claim 1.

In light of the above considerations, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §102(e).

A version with markings to show changes is enclosed.

Applicant : Lieping Chen
Serial No. : 09/451,291
Filed : November 30, 1999
Page : 7

Attorney's Docket No.: 07039-187001

CONCLUSIONS

Applicant submits that the pending claims patentably define the invention. Applicant requests that the Examiner reconsider the rejections set forth in the Office Action, and permit the pending claims to pass to allowance.

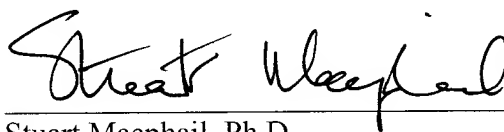
If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's undersigned representative can be reached at the telephone number listed below.

Enclosed is a petition for an automatic extension of time with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: _____

10/9/01



Stuart Macphail, Ph.D.

Reg. No. 44,217

Fish & Richardson P.C.
45 Rockefeller Plaza, Suite 2800
New York, NY 10111
Telephone: (212) 765-5070
Facsimile: (212) 258-2291

Version with markings to show changes made

In the specification:

The following heading and paragraph have been added on page 1, after the title of the application ("B7-H1, A Novel Immunoregulatory Molecule):

--Statement as to Federally Sponsored Research

Work on this invention was supported by NIH Grant Number CA79915. Therefore the government may have certain rights in the invention.--

In the claims:

Claims 2 and 3 have been cancelled.

Claims 1, 4, and 5 have been amended as follows:

1. (Amended) An isolated DNA comprising:

(a) a nucleic acid sequence that encodes a polypeptide with the ability to co-stimulate a T cell, wherein the [nucleic acid sequence hybridizes under stringent conditions to the complement of a sequence that encodes a] polypeptide [with] is (i) an amino acid sequence [with] consisting of SEQ ID NO:1 or SEQ ID NO:3 or (ii) the amino acid sequence but with one or more conservative substitutions; or

(b) the complement of the nucleic acid sequence.

4. (Amended) The DNA of claim 1, wherein the nucleic acid sequence [has] is a nucleotide sequence consisting of SEQ ID NO:2.

5. (Amended) The DNA of claim 1, wherein the nucleic acid sequence [has] is a nucleotide sequence consisting of SEQ ID NO:4.

Please add new claims 45-51.

--45. (Newly Added) An isolated DNA comprising:

(a) a nucleic acid sequence that encodes a polypeptide with the ability to co-stimulate a T cells, wherein the nucleic acid sequence is at least 50 nucleotides long and wherein the polypeptide consists of (i) a functional fragment of an amino acid sequence consisting of SEQ ID NO:1 or SEQ ID NO:3 or (ii) the functional fragment but with one or more conservative substitutions; or

(b) the complement of the nucleic acid sequence.

46. (Newly Added) The DNA of claim 45, wherein the functional fragment consists of (i) SEQ ID NO: 1 but lacking amino acid residues 1-22 of SEQ ID NO:1 or (ii) SEQ ID NO:3 but lacking amino acid residues 1-22 of SEQ ID NO:3.

47. (Newly Added) A vector comprising the DNA of claim 45.

48. (Newly Added) The vector of claim 47, wherein the nucleic acid sequence is operably linked to a regulatory element which allows expression of said nucleic acid sequence in a cell.

49. (Newly Added) A cell comprising the vector of claim 47.

50. (Newly Added) A cell comprising the vector of claim 48.

51. (Newly Added) A method of producing a polypeptide that co-stimulates a T cell, the method comprising culturing the cell of claim 50 and purifying the polypeptide from the culture.--